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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,019	10/17/2000	Max Rombi	017753-128	4184

7590 10/02/2003

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EXAMINER	
PATTEN, PATRICIA A	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 10/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/601,019	ROMBI, MAX	
	Examiner	Art Unit	
	Patricia A Patten	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,16 and 25-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,25 and 26* is/are rejected.

7)☒ Claim(s) *5,16,27 and 28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1, 3, 5, 16 and 25-28 are pending in the application and were examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 5, 16 and 25-28 are newly rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition for *treating* obesity with an extract of green tea comprising 20%-30% catechols expressed as epigallocatechin gallate (EGCG) and a caffeine content of 5%-10% by mass wherein the concentration of catechols to the concentration of caffeine in the extract of green tea is between 2 and 10, does not reasonably provide enablement for *curing* or *preventing* obesity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Inventions targeted for human therapy bear a heavy responsibility to provide supporting evidence because of the unpredictability in biological responses to therapeutic treatments. The standard of enablement is higher for

such inventions because effective cures and prevention for disease conditions are relatively rare, and may be unbelievable in the absence of strong supporting evidence.

Prevention of diseases such as obesity is highly unpredictable, because 'prevention' essentially means that the composition of the Instant invention would necessarily cease the disease from happening. Applicants have not provided data which would conclude that the extract of the Instant claims 'prevented' obesity. Typically, 'prevention' can be assessed via protocols which evaluate the statistic onset of a disease after drug administration compared with a control. No such studies were present in the Instant specification. The term 'cure' indicates the ending/completion of a disease state. The state of the art regarding curing and preventing obesity is unpredictable as evidenced by Judy Foreman in the Boston Globe, 2002: "After all the hoopla, all the hype, all the hope, and all the research, anti-obesity drugs, at least so far, have largely been a bust. And barring some secret miracle concoction now in development, there will simply not be a pharmaceutical fix for fatness in the near future" (p.2 of 3). The article further quotes Dr. Eric Colemen of the FDA as stating that "There is certainly nothing on the horizon in terms of a drug that will solve obesity"(p.2 of 3). Considering the unpredictability of the disease state itself, the Instant specification would necessarily need to provide substantial evidence of curing and preventing obesity in order to comply with the scope of enablement under 35 U.S.C. 112 First paragraph.

The Instant specification has not disclosed any evidence which would conclude that the extract obtained from green tea cured or prevented obesity. Lacking any guidance in the Instant specification with regard to working examples, coupled with the unpredictability of the disease of obesity, the skilled artisan would need to perform undue experimentation in order to use the invention commensurate in the scope of the claimed invention.

Claim Rejections - 35 USC § 102

Claims 1, 3, 25 and 26 remain rejected under 35 U.S.C. 102(b) as being anticipated by Yasuda et al. (1991) for the reasons set forth in the previous Office Action.

Applicant's arguments were fully considered, but not found persuasive.

Applicant's principal argument resides in the contention that the composition as Instantly claimed is different than that of the green tea 80% ethanol extract of the prior art. Applicant argues that the term 'green tea' is generic for an extremely broad class of at least several hundred plant varieties, all deriving from the *C. sinensis* plant: "...all green teas are not created equal..." (p. 1- Arguments). Applicant further points out that the Declaration (filed 11/16/03 points out that several green teas were subjected to 80% ethanolic

extraction, and not all of the products were found to contain the Instantly claimed percentages of EGCG and caffeine. (p.5- Arguments).

As it was pointed out in the previous Office Action, the Examiner agrees that different varieties of *C.sinensis* will probably have different amounts of catechins and caffeine, especially in evidence of the Declaration filed 11/16/03. However, it is reiterated that the Instant specification teaches that the green tea which was used was *Camellia sinensis* : "This objective has been achieved in accordance with the present invention by means of a composition for the curative and prophylactic treatment of obesity, comprising an extract of green tea, Camellia sinensis, which is rich in catechols" (p.4, Instant specification).

It is urged that *Camellia sinensis, is not Camellia sinensis* var. *assamica* (a.k.a., *Camellia assamica*) or any other variety of *Camellia sinensis*. *Camellia sinensis* and *Camellia sinensis var. assamica* are ***two different*** *varieties* of plant as is evidenced by their respective botanical classifications. Additionally, the term 'green tea' means '*Camellia sinensis*' and not '*Camellia sinensis* var. *assamica*' or '*Camellia assamica*' or any other variety of *Camellia sinensis.* In evidence, Applicant is directed to the Physician's Desk Reference for Herbal Medicines which indicates that green tea *is Camellia sinensis* (p.710). Further, The Complete Guide to Herbal Medicines also clearly teaches that green tea is *Camellia sinensis* (p.253).

It is noted that the claims are examined in light of the Specification. In the Instant case, Applicants have *taught* that an 80% ethanolic extract of green tea (*C.sinensis*) produces the claimed composition. Applicant has *not* taught an 80% ethanolic extract of *Camellia sinensis* var. *assamica* or any other variety of *Camellia sinensis*. Therefore, this rejection stands because the prior art taught an 80% extract of green tea (*Camellia sinensis*).

Applicants cite excerpts from *Ex parte Cyba*, E*x parte Skinner* and *In re Oelrich* : 'It is well established that in order for prior art to anticipate a claimed invention the inherency must be certain' ; 'The fact that a prior art article "may" inherently have the characteristics of the claimed product is not sufficient'; 'Inherency must be a necessary result and not merely a possible result' (paragraph bridging pages 5-6). In light of the Specification, it is deemed that the product disclosed by Yasuda et al. obtained via the 80% ethanolic extraction of green tea is certain to contain the claimed ranges of catechols and caffeine, because it is the *same* extraction performed on the *same* plant matter. Therefore, the product of the Yasuda et al. possesses the claimed amounts of catechols and caffeine as a 'necessary result' of the green tea having been extracted with 80% ethanol:

In view of **In re Sussman, 141 F. 2d 267, 60 U.S.P.Q. 538 (CCPA 1944):** "since the steps are the same, the results must inherently be the same unless they are due to conditions not recited in the claims." In the particular case,

Applicant is claiming an invention employing the **same process steps** but the product is ***alleged* to be different**.

Applicant argues that they have demonstrated that the 80% ethanol extraction is not an 'accurate indicator' to conclude that Yasuda et al. disclosed a composition comprising 20% to 50% by mass of catechols expressed as EGCG and from 5% to 10% of caffeine (p. 6-Arguments). Applicant argues that Yasuda et al. separately fractionated the catechins (p.6-Arguments). While this is true, Yasuda et al. nevertheless performed the 80% ethanol extraction on the green tea, and therefore were in possession of the claimed composition even though this product was an intermediate in the purification of catechins. Applicant argues that the proportion of caffeine as a part of the synergistic combination was not mentioned in Yasuda et al.. Again, it is reiterated that the amount of caffeine in the extract disclosed by Yasuda et al. would have inherently contained the range of caffeine as recited in the Instant claims because it is the same extract.

It is noted that the information presented in the Declaration is not part of the Specification, and the Specification does not contemplate the use of any green tea besides *Camellia sinensis*. Therefore, the claims were examined on the merits in light of the scope of the Specification which taught that the composition was made via an 80% ethanolic extraction of green tea (*C.sinensis*). Upon examination, it has been deemed that an 80% ethanolic extraction of green

tea (*C.sinensis*) will provide for the composition as Instantly claimed because *Applicant teaches that this is so.*

Contrary to Applicants arguments on page 7, In light of the teachings in the Specification, it is deemed that a *prima facie* case of anticipation has been established. Applicant alleges that the *C. sinensis* which was used in the Specification was 'another variety' and therefore the extract made by Yasuda et al. could not possibly anticipate the claimed invention. However, Applicants did not teach any other variety of tea besides green tea (*C.sinensis*) and therefore these arguments are not supported by any basis in the Instant specification.

Claims 1, 3, 5, 16 and 25-28 are ***newly*** rejected under 35 U.S.C. 102(a) as being anticipated by Dulloo et al. (12/1999) in light of Chantre et al. (2002)*.

Dulloo et al. (12/1999) studied the thermogenic effects of AR25, a green tea extract standardized at 25% catechins (a.k.a.'catechols') manufactured by Arkopharma Laboratories on human male subjects (p.1041). Dulloo et al. taught that the extract was an alcohol extract which contained approximately 72% of the catechol content expressed as EGCG (p.1041, col.2). Dulloo et al. explained that the extract was manufactured into capsule form containing 50 mg of caffeine and 125 mg of catechins, wherein two capsules were given to each subject at each meal, totaling 6 capsules a day which provided a daily consumption of 150 mg caffeine and 375 mg of catechins. Therefore, the extract contained a ratio of

catechins to caffeine of 2.5 (within the range specified by the claims). Dulloo et al. observed a significant increase in thermogenic response when the green tea extract was administered in comparison to the placebo or caffeine alone (p.1042, col.1 and Table 1). Please note that the extract was administered to mildly *obese* subjects as well as lean subjects. Dulloo et al. concluded that the green tea extract possessed the potential to influence body weight and body composition (p.1044).

According to Chantre et al. (2002), AR25 manufactured by Arkopharma Laboratories was an 80% ethanolic dry extract standardized at 25% catechins expressed as epigallocatechin gallate which also contained 5-10% caffeine (p.4, 'HPLC fingerprint analysis of green tea extract AR25'). Therefore, the extract contained 25% catechins. 'Standardized at 25% catechins expressed as epigallocatechin gallate' as seen in the Instant claims as well as Chantre et al., simply means that the extract was determined to possess 25% catechins measured with respect to the EGCG content: i.e., given a sample of known concentration of EGCG and other catechins, the concentration of the total amount of catechins (EGCG +other catechins such as epicatechin) in an unknown sample may be determined from a direct measurement of EGCG rather than measuring the concentration of all the catechins in solution. Total catechin content is then ascertained via extrapolation.

Although Dulloo et al. did not specifically mention the percentage of caffeine in the extract, the amount of caffeine was deemed to be an inherent property as evidenced by Chantre et al. who taught that AR25 contained 5-10% caffeine. Further, where the Instant claims state 'by mass' is further anticipated since Chantre et al. taught that AR25 was a dry extract which contained 25% catechins and 5-10% caffeine. Therefore, the AR25 used by Dulloo et al. inherently possessed 25 % *by mass* of catechins and 5-10% by mass of caffeine.

Therefore, Dulloo et al. anticipated the Instant claims in that they taught every limitation of the claims in light of Chantre et al.

*Please note that this reference is cited to relay an inherent property of AR25, and is not used in the rejection *per se*.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703) 308-1189. The examiner can normally be reached on M-F from 9am to 5pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-

3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

September 23, 2003

Patricia Patten

PATRICIA PATTEN
PATENT EXAMINER